Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0674919	03/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Old Dominion University Student Health Services	4700 Powhatan Avenue, Suite 1402, Norfolk, VA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Old Dominion University Student Health Services on March 15, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a tour/review of laboratory equipment, interviews, maintenance logs, and lack of documentation, the laboratory failed to document function checks for centrifuge revolutions per minute (RPM) for their urinalysis centrifuge during the twenty-six (26) months reviewed. Findings include: 1. During an entrance interview with the laboratory's lead tech on 3/15/22 at approximately 1:30 PM, the inspector noted a Unico Power Spin LX C858 centrifuge serial number (SN 1802432) in use for urine microscopy specimen processing. The inspector inquired of the lead tech to describe the laboratory's urine sediment examination protocol. The lead tech stated at approximately 1:40 PM: "We use the Power Spin. We centrifuge urine in the Unico dialed at the urinalysis setting of 1,500 to 2,000 RPM selection for 5 -10 minutes". 2.

	Review of the Unico Power Spin user manual revealed the following instructions: "Rotate the speed control knob slowly to the appropriate speed (Blood at 3,400 RPM, Urine at 2,000 RPM mark)". 3. Review of the laboratory's maintenance documentation revealed no records of RPM verifications for the Unico centrifuge urine setting of 2,000. The laboratory supervisor logged into Merico Biomedical Services record site and printed the following two documents: 8/10/20 SN 1802432 centrifuge speed verified by tachometer 4000 RPM. 8/13/21 SN 1802432 centrifuge speed verified by tachometer 3000 RPM. The inspector requested to review the laboratory's centrifuge calibration protocol and centrifuge verification records for the urinalysis RPM range during the review timeframe (January 2020 to the date of the inspection). No documentation was available. 4. An exit interview with the laboratory supervisor on 3/15/22 at approximately 4:30 PM confirmed the above findings.